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## *VACCINE QUALITY AND SUSTAINABILITY OF IMMUNIZATION PROGRAMMES IN THE NEWLY INDEPENDENT STATES AND THE BALTIC COUNTRIES*

Report on a WHO Working Group

**Berlin**

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## TARGET 5

### REDUCING COMMUNICABLE DISEASE

*By the year 2000, there should be no indigenous cases of poliomyelitis, diphtheria, neonatal tetanus, measles, mumps and congenital rubella in the Region and there should be a sustained and continuing reduction in the incidence and adverse consequences of other communicable diseases, notably HIV infection.*

### ABSTRACT

The Working Group was convened by the Regional Office with financial support from the Government of Germany and the Interagency Immunization Coordinating Committee (IICC). Logistic support was provided by the Robert Koch Institute, Berlin. The participants included representatives of 15 countries and their international partners: WHO, UNICEF, the International Federation of Red Cross and Red Crescent Societies, the US Agency for International Development (USAID), Basic Support for Institutionalising Child Survival (BASICS) and the Centre international de l'enfance et de la famille (CIDEF).

Sustainability of national immunization programmes is an achievable target for all the countries. This should entail national responsibility for the quality of vaccines distributed in the country through a national control authority constituted by law. Regional collaboration will facilitate this task. The Working Group noted that some of the NIS and Baltic countries are becoming independent in vaccine supply. Countries most in need are still dependent on donor support, however, and this will be facilitated by a national interagency immunization coordinating committee. The Group recommended that the implementation of WHO/UNICEF policy on the safety of injections should be considered by all countries, through a set of practical measures, in order to prevent adverse events following immunization.

### Keywords

VACCINES – standards  
QUALITY CONTROL  
IMMUNIZATION PROGRAMS  
COMMONWEALTH OF INDEPENDENT STATES  
BALTIC STATES

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## INTRODUCTION

The Working Group met to exchange information on the best ways of coming closer to the goal of sustainable immunization programmes. The meeting was convened by the WHO Regional Office for Europe with financial support from the Government of Germany and the Interagency Immunization Coordinating Committee (IICC) and logistic support from the Robert Koch Institute, Berlin. The participants included representatives of 15 countries (the newly independent states of the former USSR (NIS) and the Baltic countries) and their international partners: the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the International Federation of Red Cross and Red Crescent Societies, the US Agency for International Development (USAID), Basic Support for Institutionalising Child Survival (BASICS) and the Centre international de l'enfance et de la famille (CIDEF). The meeting was opened by Professor Burger, Deputy Director of the Robert Koch Institute, Berlin. Dr Michael Schwanig of the Paul Ehrlich Institute, Langen, Germany, chaired the meeting. Dr Massimo Ciotti served as Rapporteur and Professor Sieghart Dittmann acted as Secretary. The programme is given in Annex 2 and the list of participants in Annex 3.

### Sustainability of immunization programmes

Sustainability is one of the most important objectives of a national strategy to prevent infectious diseases through immunization. The development and maintenance of political will at government level is an important precondition for elaborating and adopting a national immunization strategy aimed at achieving sustainability. The mobilization of politicians, community leaders, leading physicians and health care workers helps to provide credibility and resources for immunization programmes. The most frequently identified issues in relation to sustainability are those concerned with financing, the supply of vaccines and other commodities and their quality control, and immunization delivery.

Following the dissolution of the USSR, the majority of the NIS and the Baltic countries received – and many still receive – support from the international donor community for primary immunization programmes in children and for disease control. These joint efforts have led to increasing coverage rates in children, a sharp decrease in the incidence of diphtheria, and all countries coming closer to the goal of poliomyelitis elimination. Important steps have been taken by many countries in implementing licensure and vaccine quality control procedures, in revising immunization schedules and the list of contraindications, and in developing a new legal basis and guidelines for immunization. Some countries have become partly or even fully self-sufficient in the provision of vaccines.

## VACCINE SUPPLY AND QUALITY CONTROL

### Vaccine supply plan

The goal of a **national supply plan** should be to ensure that adequate quantities of high quality vaccines are available to meet the short- and long-term needs of the programme. All interested parties, including the government, donors, vaccine producers and technical agencies, should participate in preparing the plan. Each plan needs to look at current and future demands for vaccines, potential supply sources and methods of financing. Estimating when the programme will

adopt a new vaccine is particularly difficult for most countries but depends on the disease burden, the willingness to address the need and the availability of financial resources.

In considering the source of supply there must be no compromise on quality. A source must be able to provide safe and effective vaccines consistently, and the vaccines should be available when needed and in the form required by the programme.

Vaccines are either provided by a national producer or are imported. Imported vaccines may be purchased by the government either directly, through a commercial agent, or through international agencies such as UNICEF. Countries should move towards independence in vaccine provision; how independent a country becomes depends on its available skills and resources.

Each country should pay for its vaccines. Vaccines are too important to leave to anyone but the national government. Because donor-dependent financing mechanisms have been popular in the past, some countries will need some time to change to an independent system. Generally, there are four mechanisms available to countries.

- A national budget line will guarantee that the programme will be able to purchase needed vaccines.
- Because of the long-term benefit, many countries are eligible to receive international development loans, which may be spent on vaccines.
- Some countries are still dependent on financial donations, but they should move towards independence as soon as possible.
- Donation of vaccines may seem attractive but is the least sustainable or nationally controllable of the options.

Timing of procurement is critical to the success of vaccine delivery. The entire planning process should remain under the control of the national programme, which should coordinate the different steps: approval of the vaccine forecast, the selection of vaccines and the supply process, and the approval and release of funds.

### National control functions depending on vaccine source

One of the targets of the Global Programme for Vaccines and Immunization (GPV) at WHO headquarters is that by the year 2000, all vaccines used in the Expanded Programme on Immunization (EPI) will be of known good quality. Currently the percentages range from 70% for hepatitis B vaccine to 81% for measles vaccine.

The strategy for reaching this target includes strengthening the functions of national control authorities (NCAs), giving advice to United Nations agencies on the acceptability of vaccines proposed for purchase (pre-qualification), instituting a vaccine donations policy, assisting countries buying vaccines with training in good procurement practices, assessing the viability of local producers, and providing training and technical advice through GPV's Global Training Network.

Vaccines of known good quality are those licensed, controlled and released by an NCA that exercises the following six critical control functions determined by the WHO Expert Committee on Biological Standardization, and where no unresolved quality problems are reported:

- a published set of requirements for licensing
- surveillance of vaccine field performance



- system of lot release
- use of laboratory when needed
- regular inspections for good manufacturing practice (GMP)
- evaluation of clinical performance.

More than 60% of DPT vaccine used is produced within the country in which it is used, the remaining 40% being fairly equally divided between importation through UNICEF and direct procurement. All vaccine obtained through UNICEF is of known good quality. Overall, however, only 73% of DPT vaccine used in the world is of known good quality, due mainly to the lack of an effective national control system in some countries.

Almost half of the world's supply of measles vaccine is produced in the countries in which it is used; direct procurement and through UNICEF account for the remainder. Some 81% of measles vaccine used worldwide is of known good quality.

Whether the six national control functions need to be exercised in a given country depends on the source of the vaccine used. If the vaccine is produced by the country itself, the NCA needs to carry out all six functions. If the vaccine is procured, GMP inspections are generally not possible and evaluation of clinical performance is not strictly needed. When the vaccine is procured through or donated by UNICEF, only licensing and the surveillance of field performance are needed. These two functions have to be carried out in any country using vaccines; for the other functions the country can rely on the WHO system used to pre-qualify suppliers of vaccine to UNICEF. There are still large gaps: of 88 countries receiving any vaccines from UNICEF, only 12 (14%) carry out these two functions.

WHO suggests that countries in need develop their policy on donations. At least four items should be included in the policy: that the use of the vaccine be epidemiologically sustainable; that it be subject to the prescribed licensing and control procedures; that it meet all other specifications consistent with vaccines already being used in the programme, including potency, presentation, transport and shelf-life; and that it not be shipped without the consent of the responsible national official. WHO Regional Offices are ready to assist countries in developing national policies on donations.

Countries where the supply sources include the production of vaccines should carry out all the six NCA functions, could participate in the Global Training Network and be part of regional laboratory networks.

The Vaccine Supply and Quality Unit (VSQ) at WHO headquarters therefore recommends that the major responsibility for vaccine quality rests with the countries themselves. WHO will provide coordination and technical resources as part of its normative functions. Donors and governments should focus on the assurance of quality through national control systems prior to further investment in vaccine production, and so reinforce WHO policy in this area.

### Global Training Network

This is an initiative of GPV/VSQ to improve the quality of locally produced vaccines. The Network consists of several institutions providing training in priority areas for vaccine production and control, using an approved syllabus and standardized documentation materials.

The objective of the Network is to ensure, by the year 2000, that all vaccines used in national immunization programmes are of known good quality. The Network provides training in areas related to the functions of an NCA for vaccine producers who meet the minimum criteria and for NCAs and laboratories. Countries should participate in the Network to develop a more sophisticated institutional knowledge base and to build relationships with other vaccine control or production institutions. Moreover, the Network will build long-term links between WHO, the trainees and the training institutions. All national control staff and vaccine producers from countries with independent NCAs are eligible to participate in the Network. Access to the Network will not be accorded to vaccine producers in those countries whose NCAs do not exercise all six critical control functions.

### Control and quality protection within vaccine procurement

In most NIS, vaccines are purchased from traditional sources or are obtained through donations and are distributed by the central government. Purchasing staff normally rely on assurances of quality from the manufacturer or the manufacturer's NCA, and have little relevant knowledge or experience themselves in the international procurement of vaccines. Financial resources for vaccine procurement are scarce and most purchasers look for low prices. In all, vaccines are now on offer for sale by more than 120 manufacturers worldwide. Manufacturers in non industrialized countries do not always produce vaccines under conditions that ensure the safety, potency and efficacy of their products. There is a significant risk of poor quality or unnecessarily expensive vaccines entering NIS immunization programmes. Procurement authorities must therefore establish safeguards and procedures to ensure that they receive high quality vaccines at the lowest possible price.

Competition is the best strategy for obtaining low prices. Participants discussed the following 11 strategies for quality protection within the procurement process.

1. Communicate, coordinate and cooperate with the NCA.
2. Pre-qualify vaccines for use in the immunization programme.
3. Decide whether firms that are not manufacturers should be allowed to supply vaccine to the immunization programme.
4. Thoroughly investigate suppliers that are not manufacturers, and pre-qualify them whenever possible.
5. Use restricted tendering procedures.
6. Develop bidding documents that emphasize and formalize quality protection.
7. Establish criteria for evaluating offers that support the procurement of high quality vaccines at the lowest possible price, while taking acceptable variables into account.
8. Include the NCA in the process of evaluating offers.
9. Include formal quality protection measures in purchase documents.
10. Monitor supplier and product performance.
11. Seek out and use tools and support mechanisms available through the international donor community and WHO.

### Manuals on vaccine procurement

Two manuals have recently been developed on vaccine procurement. The first was developed by BASICS and is intended to offer a practical approach to vaccine procurement, following a step-

by-step explanation of the procurement process. The second, developed by CIDEF in collaboration with UNICEF, AEDES, EVM and WHO, aims to strengthen the capabilities of immunization programme managers to negotiate and organize the central procurement, optimal management and distribution of vaccines at intermediate and peripheral levels. Whereas the manual developed by CIDEF is a training tool to be used in training workshops for EPI managers and supply officers, the BASICS manual is very valuable for reference purposes. The two manuals are complementary and are both sponsored by WHO.

### Vaccine donations and the role of a national interagency immunization coordinating committee

Donor agencies have provided assistance to immunization programmes within the NIS as a response to the crisis that resulted after the dissolution of the USSR. At the same time, donors have agreed to work in a way that would support the development of independent and sustainable immunization programmes in every country.

Substantial progress has been achieved in the NIS with the assistance of donor countries to improve vaccination delivery, but a great deal more remains to be done if the goals of the Kyoto Declaration are to be reached. To succeed, partnerships between donors and host countries should be formed; this will allow the identification of needs and the development of specific country plans.

In other WHO Regions, the mechanism that has proved most successful for developing this level of coordination is the national interagency immunization coordinating committee (NIICC). This is a committee chaired by a representative of the health ministry and including representatives of all the major donor agencies working in the country. The committee meets regularly to discuss plans for strengthening the national immunization programme and to identify the type of assistance needed from outside sources. This not only allows countries to inform donors of their needs, but also allows donors to make sure that they are not missing an important area of support or duplicating what other donors are doing. Other advantages of forming an NIICC are that:

- it promotes common agreement on programme objectives and strategies
- it identifies needs for additional commodity and technical support
- it helps to mobilize both national and international support
- it helps the recipient country to ensure the timely provision of commodities
- it helps donors avoid duplication, gaps and inefficiencies in humanitarian assistance, and
- it provides a forum for discussing operational, programmatic and technical issues.

In addition, the NIICC can improve coordination within the health sector, among governmental sectors, and between public and private sectors. The WHO Regional Director for Europe has recommended to the health ministers of the NIS that they should establish NIICCs and committees dealing with donor support for infectious disease control.

WHO and USAID encourage countries to establish NIICCs and health ministries to assume the leadership role in coordinating donor involvement. Countries that have not yet established an NIICC or an infectious diseases control committee are invited to follow WHO recommendations and initiate these committees.

## IMMUNIZATION DELIVERY

### The National Immunization Programme in Lithuania

In Lithuania, a National Immunization Centre was first created in 1991 under the authority of the health ministry. A National Immunization Programme and an action plan were then established to attain WHO's European health for all targets. A Centre for Communicable Diseases Prevention and Control (CCDPC) was created in January 1997, encompassing all the activities aimed at controlling infectious diseases, including immunization. The National Immunization Programme is implemented through the medical institutions in local municipalities, the Centre for Childhood Diseases at Vilnius University, and the network of outpatient medical centres, including those in rural areas. The functions of the bodies participating in the immunization activities depend on different services:

- public health and epidemiology
- selection of optimal vaccines
- research and evaluation of herd immunity
- implementation of optimal schedules
- medical networking and immunization practices
- planning and handling of vaccines
- social mobilization.

In 1992 and 1993 all the financial needs of the National Immunization Programme were covered, thanks to the support of the Danish Ministry of Foreign Affairs. Vaccines were manufactured at the Danish State Serum Institute and the French Pasteur Merieux in accordance with WHO requirements. A large quantity of vaccines as humanitarian aid was also obtained from UNICEF and certain charitable organizations (AmeriCares and Project Hope). Before independence, all vaccines had been obtained from within the USSR and the programme had a long list of contraindications. When the WHO requirements were met the list of contraindications was considerably reduced, thus allowing a very high vaccine coverage of the target population (DPT, 92.1% in 1996 vs 74.9% in 1991; OPV3, 92.6% in 1996 vs 79.7% in 1991; measles, 96.3% in 1996 vs 35.7% in 1991).

Until 1991, the vaccination schedule consisted of 22 different vaccinations at 18 different sessions to reach the desired protection. The main change with the present schedule has been to reduce the number of polio and BCG doses. As a result, the number of sessions per child have been greatly reduced, as have missed opportunities for vaccination.

Rubella and IPV vaccines have recently been introduced, and the poliomyelitis vaccination schedule is now a mixture of IPV and OPV. Hepatitis B and *Haemophilus influenzae B* vaccines will soon be introduced if the necessary financial resources are committed by the Government. Other vaccines are also offered to the population as well as the national programme, but they have to be paid for by the interested parties and are administered privately by the physician (influenza, hepatitis A, Pneumovax, meningococcal vaccine and DTaP). The cold chain is maintained by the CCDPC, which owns a central store from where distribution is organized to four regional stores and 51 MCH units which are responsible for distribution to local dispensaries.

Together with the rapid increase in vaccine coverage, morbidity from vaccine-preventable diseases has substantially decreased over the last five years. One of the most obvious indicators of

the National Programme's effectiveness is the absence of diphtheria cases since October 1996, following a large epidemic.

### The National Control Authority for Vaccines in Lithuania

The National Control Authority in Lithuania exercises independent control of the registration of pharmaceutical products, including vaccines. The process of licensing and purchasing immunobiologicals is regulated by law. The State Medicine Control Agency is responsible for supervising preclinical and clinical trials of pharmaceuticals, registering all biological products, and organizing the laboratory surveillance of pharmaceuticals, including vaccines. Applicants for registration (pharmaceutical companies, vaccine manufacturers) complete a five-part set of documentation in standard format according to guidelines issued by the European Community. This documentation specifies all the information to be provided by manufacturers for licensing any product in Lithuania.

### The National Immunization Programme in Kyrgyzstan

The National Immunization Programme is financed through the state budget and is becoming independent. The main targets are poliomyelitis eradication, elimination of diphtheria, reduction of the measles morbidity rate to less than 1/100 000 and a reduction in tuberculosis incidence. The licensing of vaccines is set out in a law which provides norms for vaccine tenders, purchase and storage. Quality control is not performed in the country, the health ministry relying on documentation provided by the manufacturers. The state is the only permitted purchaser of vaccines. EPI vaccines are covered through state funds; although aid from donors is still necessary for purchasing diphtheria vaccine for adult mass vaccination for the control of the epidemic. Mass poliomyelitis immunization was first introduced in 1995. thanks to Operation MECACAR, and some of the vaccines were supplied through donor agencies. All the vaccines used in Kyrgyzstan are purchased from external manufacturers; the only vaccine produced in the country is rabies vaccine.

### Unsafe injection practices

Some 800 million immunizations are officially given yearly in the developing world. It is estimated, however, that the total number of injections administered to children under 5 years of age is more than ten times this figure. Information reaching WHO and UNICEF consistently highlights the widespread use of unsterile injection practices and insufficient supplies of syringes, which leads to unsafe practices.

Unsafe injections can result in infectious complications such as the transmission of blood-borne pathogens. Transmission of HIV and hepatitis B virus from patient to patient, from patient to health worker and, more rarely, from health worker to patient have been reported in various health care settings. The community at large is also at risk when used injection equipment is not safely disposed of, especially if it is reused, sold or recycled. It is conservatively estimated that in the NIS, 160 million injections are performed every year and that 15% of these are unsafe, leading to 170 000 new cases of hepatitis B, 23 000 new cases of hepatitis C and 2800 new cases of HIV. The risks associated with the unsafe use of injections are mainly due to accidental needle sticks, the reuse of syringes and needles, and the lack of inadequate training of health workers. Disposable syringes are used everywhere for injection of vaccines in the NIS. The risks of using such equipment are considered high for patients and for the community. The WHO/UNICEF policy on injection safety now recommends the use of auto-destruct syringes, the risk from which

is very small for both the community and health workers and non-existent for the patient. The policy also recommends that injection practices in countries should be reviewed to assess the economic burden of unsafe practices and to establish a system to collect and incinerate used syringes and needles. Auto-destruct syringes are acceptable for vaccination campaigns where the cost is justified by safety. The syringes to be used for mass vaccination campaigns should be supplied according to a “bundling” strategy, whereby vaccines, auto-destruct syringes, safety boxes, and training and supervision are provided together. The cost of bundling for mass campaigns using Td/DT vaccines is estimated at about US \$0.18 per injection.

### Conceptual framework for preventing adverse events following immunization in the central Asian republics and Kazakhstan

In several central and eastern European countries, the NIS and the Baltic countries, adverse events following immunization have resulted in the death of infants and children over the past three years. In Denau, Uzbekistan, four children died recently following measles immunization.

An adverse event following immunization is a medical incident that takes place shortly after immunization and is believed to be caused by the vaccine. Careful investigations have shown that in the majority of cases the event was not caused by the vaccine but by programmatic errors such as secondary contamination.

A total of five clusters of adverse events following immunization have been reported to UNICEF in the CARK countries since the beginning of UNICEF involvement in the area; these have resulted in 19 deaths. In each cluster it was the same medical staff member administering the vaccine to all the children involved. It has been shown that all the clusters were caused by programmatic errors.

The fact that new such events are still being reported in the CARK justifies the urgent need for immediate and medium-term action, including the development of a training and communication package targeting health workers involved in immunization delivery. A conceptual framework for programme-related adverse events following immunization was developed based on UNICEF observations and discussions with health staff at different levels. The actions proposed require different interventions, some needing both changes in policy and the development of new administrative and/or supply systems, and most requiring the training of health workers. Recommendations for the prevention of such adverse events are included at Annex 1.

### Monitoring for effective use of resources

A well designed monitoring system including the development of a few indicators, timely feedback, ranking of performance, local analysis and local use of data can motivate staff at each level to detect and solve problems and to improve individual performance. The example of an innovative monitoring system for vaccination delivery in Kyrgyzstan was presented to the meeting.

### Information Service on Medical Supplies

The Regional Office's Information Service on Medical Supplies (ISMS) was established in 1994 following a request from the donor community. The aim of ISMS is to assist the NIS and the Baltic countries in regularly informing donors on shortfalls in medical supply for which their assistance is needed. Three areas were identified for which information would be collected: EPI

vaccines, essential drugs and basic medical equipment. The ISMS' activities with regard to EPI concern the development of a network of focal points in the NIS and Baltic countries to assess vaccine needs, supplies and utilization regularly. A set of basic indicators is used at national level to monitor different elements of the EPI programmes, such as vaccine wastage, vaccine donations, purchases and stocks. Vaccine availability is, however, influenced by many other factors: financial inputs, human resources and vaccine quality and utilization, for which other indicators may be developed to assess the rational use of vaccines.

During its three years of existence, the ISMS has been able to monitor the EPI vaccine needs and supply situation on a quarterly basis in the NIS and Baltic countries, and to inform donors about shortfalls in vaccine supplies. Over this period, a number of countries have become self-sufficient in the provision of vaccines for EPI, others are partly self-sufficient and are committing more national resources to purchasing vaccines, and a number still depend mainly on international assistance to cover EPI vaccine needs. Various factors have influenced this trend: countries have given high priority to EPI disease control, resources have been reallocated where possible, and IICC has contributed to helping countries become self-sufficient. Moreover, most countries have changed their immunization schedules to be in line with WHO recommendations. As a result of better management and coordination, the response from donors has increasingly focused on meeting real country needs. Donors have recognized the efforts made by the countries but at the same time support the further development of full self-sufficiency for EPI programmes.

Although progress has been achieved in a number of countries towards vaccine sustainability, international support will still be needed in the next biennium to ensure a high coverage of EPI immunization. The ISMS therefore proposes to continue monitoring EPI vaccine availability and rational use by countries, to continue to assist countries that require donor support, and to expand data collection to equipment needed for EPI programmes (e.g. cold chain, medical equipment). Other areas should also be identified where the financial assistance of donors may be needed to improve EPI effectiveness.

## FINANCING

### The experience of a modified type of vaccine independence initiative in the central Asian republics

In 1994, an agreement along the lines of the WHO Vaccine Independence Initiative (VII) was signed between the Government of Japan, three central Asian republics and UNICEF, as a means of re-establishing a system for supply of vaccines. The time-frame for achieving financial independence was set at five years; after the first year the three central Asian governments were already able to meet the first phase of their commitments. A special budget line was created and funds allocated to procure vaccines and other commodities related to EPI. In fact, owing to a fall in vaccine prices and a better estimation of the target population, the VII agreement was revised in 1997 to optimize the utilization of funds, and additional activities were included to be supported by financial commitments. As a result of these savings, the cold chain in Kazakhstan was reorganized to improve its storage capacity and efficiency. Procurement of syringes and needles was included in the Turkmenistan agreement, which covered the needs for 1997–2000 and left the target of achieving vaccine self-sufficiency to the original timeframe. Uzbekistan was able to provide a new estimate of needs, thus decreasing the total budget shortfall and bringing forward the target of vaccine self-reliance to the year 2000.

The VII agreement is a story of successful collaboration between UNICEF and the central Asian republics. It not only provides a long-term solution to the problem of vaccine supply, but also the financial mechanisms for governments to strengthen their overall immunization programmes. The VII also provides experience in the management of financial resources, a valuable asset in developing similar models for building sustainability into other national primary health care programmes.

### From donations to vaccine independence – the Latvian experience

The implementation of a good immunization programme has been progressing step by step in Latvia. A Law on Epidemic Security was recently adopted by Parliament, followed by draft regulations on vaccination issued by the government. A new plan of work has been adopted for the national immunization programme for the period 1998–2000, providing for vaccination against 10 childhood diseases. These vaccinations are compulsory, and the expense is totally covered by the state.

The national programme has also developed draft instructions on procedures for the planning, supply, distribution and registration of immunobiological preparations.

In 1996, the vaccine supply system was improved, allowing all 1459 medical institutions carrying out vaccinations to receive good quality vaccines on time and in the right quantity. Vaccines are stored at central level and distributed to regional stores on request. All the information related to vaccine purchase, storage and distribution is managed through a computer programme developed by the national programme. This also allows appropriate monitoring of vaccinations performed, keeping track of coverage rates by district. Vaccines are procured centrally through a bidding system by suppliers, which keeps prices low.

Health workers involved in immunization receive in-service training and a national bulletin is published regularly to provide feedback to the peripheral level. Brochures and posters are also produced to mobilize the public on immunization issues.

## CONCLUSIONS AND RECOMMENDATIONS

1. To ensure the sustainability of a national immunization programme, national vaccine supply plans should be developed that include, both in the short and long term:
  - the financial basis of the programme, with the aim of reducing reliance on outside donor support;
  - the supply of vaccines (and other commodities) and their quality control, depending on their source; and
  - all aspects of immunization delivery.
2. Each country should assume responsibility for overseeing the quality of vaccines used in its national immunization programme through a legally constituted national control authority (NCA). The complexity and functions of the NCA will depend on the source of vaccines used in the country. In most countries, vaccine quality control is one of the tasks of the national drug control authority.
3. Recognizing that each country has ultimate responsibility for assuring vaccine quality, regional and subregional collaboration should be explored to facilitate this task.



4. Because of the special nature of vaccines, their procurement is a complex process requiring specific technical inputs. Two complementary manuals developed by BASICS and CIDEF will be useful for countries procuring vaccines.
5. Innovative methods to ensure increasing national financing of vaccine supply, such as the Vaccine Independence Initiative and the planning and monitoring activities that go with it, can strengthen the immunization programme and help to achieve self-sufficiency.
6. Some of the NIS and Baltic countries are becoming self-sufficient in vaccine supply. Continued monitoring by the Regional Office facilitates identification of recent progress, not only in the provision of vaccines but as regards other components of the immunization programme.
7. There is still a need to provide future donor support for those countries most in need (for poliomyelitis eradication, diphtheria control, primary immunization) and for emergency response in case of outbreaks and epidemics.
8. Donor coordination through national interagency immunization coordinating committees (NIICC) will help both countries and donors to ensure that donor support for immunization, or for infectious diseases control that includes immunization, is constructive and avoids duplication of efforts.
9. Countries are encouraged to develop a representative working group and a process to engage health staff at various levels to examine the existing immunization information system and to design, test, revise and introduce a monitoring system for all aspects of the immunization programme, including the efficient use of resources.
10. Countries can take several constructive courses of action to ensure the safety of injections, including assessing the current status of injection practices, taking measures for proper syringe disposal, requesting “bundling” of vaccine donations with auto-destruct syringes and safety boxes, and reviewing immunization schedules to minimize unnecessary injections. The WHO/UNICEF policy on safe injections should be followed.
11. UNICEF recommendations to improve the safety of immunizations (see Annex 1) should be considered by all countries in order to prevent adverse events following immunization.
12. National capacities to investigate adverse events following immunization, to draw conclusions on their causes based on epidemiological data, and to correct unsafe immunization practices should be strengthened.
13. In case of severe adverse events following immunization, careful investigations should identify all relevant circumstances related to the event. While vaccine testing may give complementary data, in most such instances conclusions can be drawn and decisions taken on corrective actions and whether to continue or interrupt immunization with the implicated lot of vaccine in the absence of laboratory testing.

*Annex 1*

## UNICEF RECOMMENDATIONS TO IMPROVE THE SAFETY OF IMMUNIZATIONS

<b>Policy</b>	<b>Systems development</b>	<b>Supplies</b>	<b>Training</b>
<ul style="list-style-type: none"> <li>Promote open vial policy</li> </ul>	<ul style="list-style-type: none"> <li>Implement open vial policy</li> </ul>	<ul style="list-style-type: none"> <li>Provide kits to all health centres for the treatment of anaphylactic shock</li> </ul>	<ul style="list-style-type: none"> <li>Improve undergraduate and postgraduate curricula in EPI activities</li> </ul>
<ul style="list-style-type: none"> <li>Change distribution strategy for syringes and needles</li> </ul>	<ul style="list-style-type: none"> <li>Develop supervisory systems for all health staff</li> </ul>	<ul style="list-style-type: none"> <li>Provide thermometers to all health centres</li> </ul>	<ul style="list-style-type: none"> <li>Improve written material from the health ministry on safe immunization practices</li> </ul>
<ul style="list-style-type: none"> <li>Permit mothers to buy syringes and needles in health centres</li> </ul>	<ul style="list-style-type: none"> <li>Develop new stock management system</li> </ul>	<ul style="list-style-type: none"> <li>Arrange for new supplies to replace those lost in electricity failures</li> </ul>	<ul style="list-style-type: none"> <li>Develop workshops to train in safe immunization practices</li> </ul>
<ul style="list-style-type: none"> <li>Make up-to-date information about vaccines available to health centres</li> </ul>	<ul style="list-style-type: none"> <li>Implement new distribution system for syringes and needles</li> </ul>	<ul style="list-style-type: none"> <li>Supply syringes and needles to health centres for purchase by the public</li> </ul>	<ul style="list-style-type: none"> <li>Develop and prepare human resources for supervision of staff</li> </ul>
<ul style="list-style-type: none"> <li>Provide adequate anaphylaxis kits</li> </ul>			<ul style="list-style-type: none"> <li>Train in open vial policy</li> </ul>
<ul style="list-style-type: none"> <li>Develop policy on management of stock during electricity failures</li> </ul>			<ul style="list-style-type: none"> <li>Training in communication skills treatment of anaphylactic shock</li> </ul>

*Annex 2*

**PROGRAMME**

***Wednesday, 12 November 1997***

**Opening**

On behalf of host country	Professor Reinhard Burger Robert Koch Institut
On behalf of WHO	Dr Sieghart Dittmann, WHO/EURO
Election of chairperson and rapporteur	
What is the meaning of “sustainability of immunization programmes”	Dr Sieghart Dittmann, WHO/EURO

**Vaccine supply and quality control**

Vaccine supply plan	Peter Evans, WHO/GPV/VSQ
National control functions depending on vaccine source	Dr Julie B. Milstien, WHO/GPV/VSQ
The global training network – why you should participate	Dr Julie B. Milstien, WHO/GPV/VSQ
Procurement of vaccines – control and quality protection within vaccine procurement	Dian Woodle, USAID/BASICS
Information on manuals	Dr Nicole Guérin, CIDEF, Dian Woodle and Robert Steinglass, USAID/BASICS
Vaccine donations and the role of a national interagency coordination committee	Robert Steinglass, USAID/BASICS

***Thursday, 13 November 1997***

**Immunization delivery**

National centre for immunoprophylaxis Kyrgyzstan Lithuania	Dr V. Bakasenas
Unsafe injections practices: today’s and tomorrow’s challenges of immunization and health programmes	Michel Zaffran, WHO/EPI
Conceptual framework to prevent adverse events following immunization in Central Asian Republics and Kazakhstan	Dr Umit Kartoglu, UNICEF/CARK
Monitoring for effective use of resources	Robert Steinglass, USAID/BASICS

Information system on medical supplies

Dr J.-N. Ormsby, WHO/EURO

**Financing**

The experience of a modified type of vaccine  
independence initiative in Central Asian Republics

Stéphane Guichard, UNICEF CARK

The vaccine independence initiative in a  
central Asian republic

Dr Kembabanova, Kazakstan

How to go from donations to vaccine independence

Dr J. Perevoscikovs, Latvia

Conclusions and recommendations

**Closure of the Meeting**

*Annex 3*

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